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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/415,966	10/12/1999	STEVEN A. BENNER	SUL-402D1	5522

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EXAMINER

ARTHUR, LISA BENNETT

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/21/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/415,966

Applicant(s)

BENNER, STEVEN A.

Examiner

Lisa B. Arthur

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3,4 and 7-30 is/are pending in the application.
- 4a) Of the above claim(s) 10-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3,4 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1655

1. This action is in response to the paper filed October 4, 2001. Claims 1,2,5 and 6 have been canceled. Currently, claims 3,4,7-31 are pending. However, newly added claims 11-30 have been withdrawn from consideration by the restriction requirement included below. This application includes and examination of claims 3,4,7-9. Any rejections which have not been reiterated have been withdrawn. This action contains new grounds for rejection and is therefore not final.

RESTRICTION REQUIREMENT

2. Newly submitted claims 11-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

I Claims 3,4,7-9 are drawn to a method for creating ligands, classified in class 435, subclass 6.

II Claims 11-20 are drawn to oligonucleotides containing non-natural bases, classified in class 536, subclass 24.3

III Claims 21-30 are drawn to methods of making oligonucleotides by incorporating on-natural bases using a polymerase, classified in 435, subclass 91.1.

The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

Art Unit: 1655

§ 806.05(h)). In the instant case the oligonucleotides can be used in a materially different process such as a hybridization method for detecting and/or purifying complementary nucleic acids.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the oligonucleotide can be made by a materially different process such as solid phase synthesis.

Inventions I and III are patentably distinct methods because they have different objectives, different method steps and different reagents. The method of invention uses non-natural nucleotides to synthesize oligonucleotides which are then contacted with a target to identify oligonucleotides with increased affinity for other oligonucleotides in a mixture and amplifying those oligonucleotides. Invention II is drawn to a method for synthesizing a group of oligonucleotides by adding nonnatural bases to an oligonucleotide with a polymerase. Invention II does not involve hybridizing oligonucleotides to identify oligonucleotide with increased affinity for another oligonucleotide. Therefore, these inventions are novel and unobvious over one another.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Art Unit: 1655

NEW GROUNDS OBJECTION

3. Claims 3 and 4 are objected to because they are dependent upon a canceled claim. This objection can be overcome by amending the claims to include the text of claim 1 in the body of claims 3 and 4.

4. Claims 7 and 8 are objected to because they are dependent upon a canceled claim. This objection can be overcome by amending the claims to include the text of claim 6 in the body of claims 7 and 8.

NEW GROUNDS OF REJECTION

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) In step (b) the recitation of “amplifiable to oligonucleotides” makes the claims unclear as to what chemical transformation is occurring and what the conditions of incubation are. The

Art Unit: 1655

phrase “amplifiable to oligonucleotides” does not make grammatical sense and thus makes the meaning of the claim unclear.

B) In step (e) the recitation of “binds noncovalently to the oligonucleotides so enriched” makes the claims unclear because “oligonucleotides so enriched lacks antecedent basis” As a result. No enrichment step has occurred in step (b) and as a result, it is unclear as to which oligonucleotides to cofactor binds to.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3,4,7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide sufficient guidance to enable the skilled artisan to make and use the claimed methods without undue experimentation because of the unpredictability of a polymerase to incorporate a non-natural nucleotide into a polynucleotide. The specification teaches how to make several different uridine analogs modified at the 5 position. The specification states that Klenow fragment can incorporate many pyrimidines at the 5' position. The specification also teaches that the functionalized cofactors can be added to a library to modify

Art Unit: 1655

a nucleotide which is "less demanding on the polymerase". The methods are drawn involve not only the incorporation of modified nucleotides into an oligonucleotide but also the amplification of these oligonucleotides. In previous applications, the specification described the pairs of non-natural nucleotides which functioned as complementary nucleotides during polymerization and hybridization. However, the instant specification contains no teaching that the modified uridine nucleotides pair with a specific modified or natural purine. The specification does not actually demonstrate that the claimed nucleotides can be incorporated into a polynucleotide by a polymerase or that oligonucleotides containing these modified nucleotides can function as templates in an amplification reaction. The ability of a non-natural nucleotide to be used as a substrate by polymerases in general or a specific polymerase was highly unpredictable and unexpected at the time of filing. Furthermore, these methods not only require the incorporation of non-natural bases but also their ability to anneal to other nucleotides such that hybridization and/or catalyzation (claim 9) can occur. Claim 9 is further not enabled because the claims are broadly drawn to the introduction of any organic cofactor into a mixture of oligonucleotides containing some that are catalytic. The claim is unclear as written but it appears that the cofactor is supposed to selectively bind to the oligonucleotides exhibiting catalytic activity. The specification contains no teaching as to how the organic cofactor selectively associates with only the catalytic oligonucleotides. Furthermore, it is unclear how this cofactor is to effect catalytic activity or to result in catalytic activity if the cofactor is to have any effect at all on catalytic activity. The skilled artisan would therefore be required to perform additional extensive

Art Unit: 1655

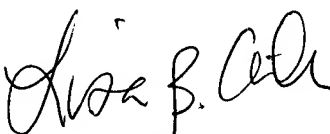
experimentation without a reasonable expectation of whether or not the modified uridine compounds would be incorporated and functional in an amplification reaction and whether the cofactors could be used in a method for identifying catalytic oligonucleotides.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800 1600

March 19, 2002